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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,088	01/18/2002	Graham John Hamilton Melrose	2354/141 (FF34527/02)	6479

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EXAMINER	
KUMAR, PREETI	

ART UNIT	PAPER NUMBER
1796	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/053,088	MELROSE ET AL.	
	Examiner	Art Unit	
	PREETI KUMAR	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,7,9-13,15-17,25-39,42,46,47 and 49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-7, 9-13, 15-17, 25-39, 42, 46-47 and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/17/2007 has been entered.

Non-Final Rejection

2. Claims 6-7, 9-13, 15-17, 25-39, 42, 46-47 and 49 are pending.

Claim 49 is newly added and independent.

Priority

3. The subject matter of the limitations of newly presented independent claim 49 are entitled to a priority date of February 16, 2000. Examiner acknowledges that the material limitations of at least independent claim 49 is entitled to a priority date of February 16, 2000 which is the filing date of 10/009,139 to which Applicants are claiming a continuation-in-part.

Response to Amendment

4. The rejection of claims 2-7, 10, 13, 16, 17, 24-25, 28, 30-31, 42, and 46-48, on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10, 18, 22, 24 and 28 of U.S. Patent No. 6,410,040 is withdrawn in light of Applicants amendment to the independent claim requiring a method step of heating.

5. The rejection of claims 2-7, 9-13, 15-17, 24-39, 42, and 44-48 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6,723,336 is withdrawn in light of Applicants amendment to the independent claim requiring a method step of heating.

6. The rejection of claims 6-7, 9-13, 15-17, 25-39, 42, and 46-47under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Melrose (WO 96/38186). See the New Grounds of Rejection addressing new independent claim 49.

Response to Arguments

7. Applicant's arguments filed 12/17/1007 have been fully considered but they are not persuasive.

Applicants urge that Melrose I fails to teach or suggest further treating the product poly(2-propenal, 2-propenoic acid) by "heating poly(2-propenal, 2-propenoic acid) in a polyol at a temperature in the range from 40°C to 150°C for a time sufficient to increase the antimicrobial activity of the poly(2- propenal, 2-propenoic acid)."

Contrary to Applicants arguments, the prior art teaching of Melrose et al. illustrates a reaction of the subject polymers poly(2-propenal, 2-propenoic acid) with polyol at room temperature upto 100 degrees C to increase hydrophilicity and utility in

the application of treating diseases of the gastrointestinal tract of humans, animals and birds. See page 3,ln.25-35 and page 7,lines 5-15 and in examples 1, 8-11,13 and 15-16. Specifically in examples 8-11 on page 10, Melrose et al. illustrate the fixing of poly(2-propenal, 2-propenoic acid), from a homopolymer of acrolein by ionic derivation and oxidation and more specifically teach heating at 60-70 C for 48 hours with methanol. More specifically, Melrose et al. illustrate the subject polymers and CARBOPOL polyol heated to 45C and suggest heating to 90-100C. See ex. 15 and 16 on page 12. Thus, the rejection over Melrose et al. (WO 96/38186) is pertinent to the material limitations of the instant claims.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 6-7, 9-13, 15-17, 25-39, 42, 46-47 and 49 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Melrose et al. (WO 96/38186).

Melrose et al. teach a method for the treatment of gastrointestinal disease and/or cancer, and a method of weight gain, via the ingestion of polymeric compositions in humans, animals or birds in need of said treatment. The invention provides methods for the treatment of cancer, the treatment and/or prevention of gastrointestinal disease and/or infection and/or diarrhea and a method for increasing weight gain in humans, animals or birds comprising administering to said humans, animals or birds an effective amount of a pharmaceutical or veterinary composition or feed additive, comprising an effective amount of a polymer and/or copolymer, having the repeating polymeric unit (I) wherein R is H or alkyl, usually C.sub.1 to C.sub.4, or this unit in hydrated, hemiacetal or acetal form, together with a pharmaceutically or veterinarally acceptable carrier, diluent, adjuvant, excipient and/or controlled release system. See abstract.

Melrose et al. teach a method for the preparation of compositions of poly(2-propenal, 2-propenoic acid) comprising the method steps of dissolving the poly(2-

propenal, 2-propenoic acid) in aqueous base, adding an organic compound containing one or more hydrophobic groups, and subsequently acidifying the solution, whereby interaction between the hydrophobic groups of the organic compound and the poly(2-propenal, 2-propenoic acid) prevents precipitation of the poly(2-propenal, 2-propenoic acid) and the solution is consequently stable over a broad pH range. See abstract. Specifically, Melrose et al. teach polymeric compounds having a polyacrolein sub-unit in aldehyde, hydrated, hemi-acetal or acetal form and having biostatic or biocidal properties and the biostatic and/or biocidal uses of these compositions. See page 4, ln.5-10 and page 7,ln.20-25. Furthermore, Applicants admit in at least their remarks filed 12/17/2007 that Melrose et al. teaches forming the starting material, poly(2-propenal, 2-propenoic acid), which is fixed from a homopolymer of acrolein by ionic derivation and oxidation.

Regarding the claimed method step of heating the poly(2-propenal, 2-propenoic acid) in a polyol at a temperature of 40-150 C, Melrose et al. illustrates a reaction of the subject polymers poly(2-propenal, 2-propenoic acid) with polyol at room temperature upto 100 degrees C to increase hydrophilicity and utility in the application of treating diseases of the gastrointestinal tract of humans, animals and birds. See page 3,ln.25-35 and page 7,lines 5-15 and in examples 1, 8-11,13 and 15-16. Specifically in examples 8-11 on page 10, Melrose et al. illustrate the fixing of poly(2-propenal, 2-propenoic acid), from a homopolymer of acrolein by ionic derivation and oxidation and more specifically teach heating at 60-70 C for 48 hours with methanol. More

specifically, Melrose et al. illustrate the subject polymers and CARBOPOL polyol heated to 45C and suggest heating to 90-100C. See example 15 and 16 on page 12.

Melrose et al. teach a method of producing pellets or like solid composition, the pellets comprising polymers and/or copolymers as defined in the first embodiment of the invention, mainly within a polymeric matrix, said method as defined in the fourth embodiment of the invention and comprising the steps of: (i) dissolving said polymers and/or copolymers in an aqueous alkaline or basic solution; (ii) neutralising said solution with acid; (iii) adding to said neutralised solution insoluble, cross-linked, absorbent polymers of acrylic acid and/or copolymers of acrylamide and acrylic acid, to form wet swollen pellets; and (iv) optionally, wholly or partially drying said wet swollen pellets. The so-formed wet, swollen pellets may be used either wet, partially dried or wholly dried, as an additive to, for example, animal feed. This system is further designed so that the carboxyl-containing groups of the outer polymeric matrix cause the Subject Polymers to remain essentially contained within the matrix when in the acidic environment of the stomach. However, in the alkaline environment of the duodenum, the carboxyl groups of the matrix become ionised and mutually-repelling, and the pellet rapidly swells to allow the Subject Polymers, aided by repulsion among their own ionic groups, to be excluded by a diffusion process, approximately matching the speed of passage of feed through the duodenum. See page 7, lines 15-35.

Specifically regarding claims 6-7, 9-11, Melrose teach that the antimicrrobial composition comprises pharmaceutically or veterinarally acceptable binders, sweeteners, disintegrating agents, diluents, flavourings, coating agents, preservatives,

lubricants and/or time delay agents. Suitable binders include gum acacia, gelatin, corn starch, gum tragacanth, sodium alginate, carboxymethylcellulose or polyethylene glycol. Suitable flavouring agents include peppermint oil, oil of wintergreen, cherry, orange or raspberry flavouring. Suitable coating agents include polymers or copolymers of acrylic acid and/or methacrylic acid and/or their esters, and/or their amides, waxes, fatty alcohols, zein, shellac or gluten. Melrose teach that liquid forms for oral administration may contain, in addition to the above agents, a liquid carrier. Suitable liquid carriers include water, oils such as olive oil, peanut oil, sesame oil, sunflower oil, safflower oil, arachis oil, coconut oil, liquid paraffin, ethylene glycol, propylene glycol, polyethylene glycol, ethanol, propanol, isopropanol, glycerol, fatty alcohols, triglycerides or mixtures thereof. See page 6,ln.15-40..

Specifically regarding claims 12-13, 15 and 25 Melrose et al. teach that the antimicrobial composition is added to drinking water. See claim 11.

Specifically regarding claims 16-17, Melrose et al. teach that the composition further comprises one or more of methanol, acetone, tetra-hydrofuran, methyl ethyl ketone, benzoyl peroxide which exhibit a synergistic increase in antimicrobial activity. See examples 5-15 illustrating compositions comprising 1.5% antimicrobial polymer in 65% ethanol. See line 8 of pg.16.

Regarding claims 26-32 and 36-38, Melrose et al. teach the utility of poly(2-propenal, 2-propenoic acid) in humans, animals such as pigs, birds and mice having microbialogical diseases of the gastrointestinal tract for example E. coli, and organisms

such as Staphylococcus aureus, Helicobactor pylori, which cause gastrointestinal disease in animals. See page 8,ln.5-10.

Regarding claims 46-47, Melrose et al. teach the utility of a composition comprising poly(2-propenal, 2-propenoic acid) and polyethylene glycol as an animal feed additive. See abstract and page 7,lines 5-15.

Melrose et al. illustrate in examples 1,13 and 15 a composition comprising 30 mg benzoyl peroxide added to a solution of 1.02 g polyethyleneglycol acrylate and 0.5 ml acrolein in 5 ml methanol. The mixture was stirred and heated to reflux for 48 hours and gave 90% conversion; the residual oil (1.2 g) was chromatographed on Sephadex LH-20 (18 g) in methanol. The structure of the resulting polymer was confirmed by NMR analysis. The Subject Polymers were suspended/dissolved in the drinking water of piglets, at 0.1% w/v for the first 2-3 days and then at 0.05% w/v for the next 7 days; drinking was ad libitum; consumption of Subject Polymers was approximately 200 mg/kg of piglet/day.

Melrose et al. illustrates a composition comprising poly(2-propenal, 2-propenoic acid) in polyethylene glycol which is heated in example 13, and in example 16, Melrose et al. illustrates the subject polymers are heated with CARBOPOL polyol at 45C or 90-100C. Accordingly, the teachings of Melrose et al. anticipate the material limitations of the instant claims.

Alternatively, even if the broad teachings of Melrose et al. are not sufficient to anticipate the material limitations of the instant claims, it would have been nonetheless obvious to one of ordinary skill in the art, to arrive at an antimicrobial composition

comprising a derivative of poly(2-propenal, 2-propenoic acid) in a polyol at a temperature in the range from 40-150C for a time sufficient to increase the antimicrobial activity of the poly(2-propenal, 2-propenoic acid) as recited by the instant claims, because Melrose et al. teach a reaction of the subject polymers poly(2-propenal, 2-propenoic acid) heated with polyethylene glycol in example 13 and further teach heating the subject polymers poly(2-propenal, 2-propenoic acid) heated with CARBOPOL polyol at 45C and suggest heating at 90-100C to increase hydrophilicity and utility in the application of treating diseases of the gastrointestinal tract of humans, animals and birds. See examples 1,13, 15 and 16.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to PREETI KUMAR whose telephone number is (571)272-1320. The examiner can normally be reached on 7:30 am-3:30 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on 571-272-1119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/P. K./
Examiner, Art Unit 1796

/VASUDEVAN S. JAGANNATHAN/
Supervisory Patent Examiner, Art Unit 1796